

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

IN RE DIGITEK®  
PRODUCT LIABILITY LITIGATION

MDL NO. 1968

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THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 28  
(Motion to Quash or Modify Subpoena)

Pending before the court is the motion to quash or modify subpoena filed by defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC ("Defendants") (docket # 134). The subpoena was issued by the United States District Court for the District of New Jersey, at the request of Plaintiffs, to the Custodian of Records, Gibraltar Laboratories, Inc., of Fairfield, New Jersey. (# 134, Ex. A.) Gibraltar's role is unclear; Defendants indicate that Gibraltar "provides various laboratory services." (# 134, at 3.) Pursuant to 28 U.S.C. § 1407(b) and the holding in In re Clients and Former Clients of Baron & Budd, P.C., 478 F.3d 670 (5th Cir. 2007), it is appropriate for this court to address issues arising with respect to an MDL case subpoena.

Positions of the Parties

Defendants ask the court to quash or modify the subpoena because it calls for the production of documents and information relating to products other than Digitek®, which constitute

"'privileged or other protected matter' under Pretrial Order # 12 ('PTO # 12") and Rule 45(c)(3)(A)(iii)," *Fed. R. Civ. P.* (# 134, at 1, 2.) By Order entered June 4, 2009 (# 135), the court stayed the subpoena pending briefing and a ruling on the motion.

Defendants assert that the subpoena should be quashed or modified because they are entitled to redact information and documents pursuant to PTO # 12, and the contract between defendant Actavis Totowa LLC and Gibraltar which acknowledges the exchange of confidential information and contains provisions relating thereto. They note that the subpoena is not restricted to production of Digitek®-related documents, and that Plaintiffs have not shown good cause to expand the scope of discovery beyond Digitek®. (# 134, at 4-5.)

Plaintiffs' response contends that PTO # 12 does not authorize Defendants unilaterally to redact information from a third party. (# 136-1, at 5-6.) They also assert that the scope of discovery should be expanded to include all manufacturing processes for all product lines at Defendants' Little Falls, New Jersey facility. Id., at 6-9. Finally, Plaintiffs suggest that the court should review the documents produced by Gibraltar. Id., at 9.

Defendants' reply argues that Plaintiffs' response contains no evidence or argument that prevents the court from granting Defendants' motion. (# 139, at 1.) They rely on the terms of PTO # 12 and the contract with Gibraltar to support their right to

review all Gibraltar's records responsive to the subpoena, and to redact information before production to Plaintiffs. Id., at 2.

#### Applicable Orders and Rules

The scope of discovery has been briefed by the parties. In Pretrial Order # 27, the court expanded the scope of discovery to include product batches the production of which immediately preceded the production of Digitek® batches, using any of the same equipment. The court will now apply that ruling to PTO # 12 and applicable rules.

PTO # 12 contains several provisions which are applicable to the issue presented here.

#### **I. Scope of Order**

\* \* \*

- C. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Supplying Party for purposes of this Protective Order.
- D. The entry of this Protective Order does not preclude any party from seeking a further order of this court under Federal Rule of Civil Procedure 26(c).

#### **II. Designation and Redaction of Confidential Information**

- A. "Confidential Information" as used herein means any information that the Supplying Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Federal Rule of Civil Procedure 26(c) or other applicable law, whether it is a document (electronic or otherwise), information contained in a document, information revealed during a

deposition or other testimony, information revealed in an interrogatory response or information otherwise revealed. In designating materials as "CONFIDENTIAL," the Supplying Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the court.

- B. Specific documents and discovery responses produced by the Supplying Party shall, if appropriate, be designated as "CONFIDENTIAL" by marking the pages of the document that contain Confidential Information as follows: "CONFIDENTIAL" or "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER."

\* \* \*

- D. A party in this proceeding may designate as Confidential Information any document or information produced by, or testimony given by, any other person or entity that the party reasonably believes qualifies as such party's Confidential Information under this Protective Order. If any third party produces information that any party in good faith believes constitutes its Confidential Information, the party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any party receiving information from a third party shall treat such information as confidential during this thirty (30) day period while all parties have an opportunity to review the information and determine whether it should be designated as confidential. Any party designating third party information as confidential shall have the same rights as a Supplying Party under this order with respect to such information.

\* \* \*

- F. To protect against unauthorized disclosure of Confidential Information, and to comply with all applicable state and federal laws and regulations, the Supplying Party may redact from produced documents, materials or other things, or portions thereof, the following items, or any other item(s) agreed upon by the parties or ordered by the court:

\* \* \*

2. Highly confidential trade secrets such as those related to the formulation of Digitek®, unless such formulation also appears in the ANDA for Digitek;
3. Highly confidential business and proprietary

- information related to sales data of the named Defendants, except sales data of Digitek;
4. Any information relating to products other than Digitek®, unless manufacturing information about a product other than Digitek is reasonably related to Digitek manufacturing; . . .

Notwithstanding any of the foregoing provisions, nothing contained herein shall be construed as a waiver of plaintiff's ability to seek an order for good cause shown compelling production of information redacted pursuant to this paragraph.

To the court's knowledge, Gibraltar has not participated in the briefing of this issue, and it has not informed the court that it has elected to become a Supplying Party pursuant to section I.C. of PTO # 12.

Rule 26(c)(1), *Fed. R. Civ. P.*, authorizes district courts to "issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (D) forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matters; . . . [and] (G) requiring that a trade secret or other confidential research, development or commercial information not be revealed or be revealed only in a specified way . . ."

The Agreement between Actavis and Gibraltar

Defendants are asserting their right under section II.D. of PTO # 12 to "designate as Confidential Information any document or information produced by, or testimony given by, any other person or entity that the party reasonably believes qualifies as such party's

Confidential Information under this Protective Order.” The Confidentiality and Proprietary Agreement between Gibraltar and Actavis Totowa, LLC, dated May 21, 2007 (“the Agreement”), contains the following relevant provisions:

**A. WHEREAS** Actavis Totowa and Gibraltar Laboratory wish to explore and discuss the potential of certain mutually advantageous business ventures; and

**B. WHEREAS** Actavis Totowa and Gibraltar Laboratory, in furtherance of such exploration and discussions, will exchange certain financial, marketing, sales, scientific, development or other proprietary information; and

**C. WHEREAS** Actavis Totowa and Gibraltar Laboratory each wish to maintain the confidentiality of such information by preventing unauthorized disclosure;

\* \* \*

#### **I. EXCHANGE OF INFORMATION**

Actavis Totowa and Gibraltar Laboratory agree to exchange such Confidential Information, as that term is defined herein, as is reasonably necessary to evaluate opportunities of mutual interest.

#### **II. DEFINITION OF CONFIDENTIAL INFORMATION**

For purposes of this Agreement “Confidential Information” means all non-public and/or proprietary information owned or possessed by the disclosing Party, whether existing before the date of this Agreement or created hereafter, including, without limitation: all notes, books, papers, diagrams, documents, reports, memoranda, concepts, formal or analytical methods, technical or scientific data, unpublished findings, biological material, know-how, specifications, processes, techniques, patent applications, algorithms, programs, designs, drawings, or formulae; any engineering, manufacturing, marketing, financial or business plan, and all other data or information in whatever form, disclosed by one Party to the other. In the case of Confidential Information disclosed by Actavis Totowa, Confidential Information shall also include Confidential Information disclosed by

or received from its subsidiaries or Actavis Group HF (collectively "Actavis Entities").

### **III. CONFIDENTIALITY**

Actavis Totowa and Gibraltar Laboratory agree that the recipient of the Confidential Information referred to in Articles I and II shall not disclose, cause, or permit the disclosure of said Confidential Information to any third party or parties, subject to the exceptions contained in Articles IV and V herein, without the prior written consent of the disclosing Party.

(# 134, Ex. B, at 1-2.)

The definition of "Confidential Information" in the Agreement is extremely broad and covers virtually every document provided by Actavis Totowa to Gibraltar and vice versa. Gibraltar basically agreed not to disclose to anyone other than its consultants, agents, and advisors any information which it received from Actavis Totowa without the prior written consent of Actavis Totowa. Clearly, Actavis Totowa has not given its written consent to Gibraltar to produce any Actavis Totowa "Confidential Information" in response to the subpoena. If Gibraltar were to disclose such Actavis Totowa "Confidential Information" in response to the subpoena, it would risk being in breach of the Agreement, and subject to "an injunction and immediate restraints against any breach, threatened breach, or potential breach . . . in addition to any other remedy . . . ." Id., Ex. B, VIII. REMEDIES, at 3. Gibraltar is under a duty to return "all Confidential Information upon the request of" Actavis Totowa. Id., IX. RETURN OF DOCUMENTS AND PROPERTY, at 3. The court has no reason to believe that

Actavis Totowa has requested return of its documents from Gibraltar. The Agreement has relevance to the dispute before the court to establish that Gibraltar possesses information which Actavis Totowa deems to be confidential; the court is not called upon to render any ruling as to the Agreement.

#### Breadth of the Subpoena

Defendants complain that the subpoena issued to Gibraltar is overbroad in that it calls for documents and records beyond Digitek®. (# 134, at 1.) Defendants do not object to the subpoena insofar as it calls for production of Digitek®-related documents. Id. Defendants point out that the subpoena defines "Digitek® (Digoxin)" as "the brand-name of one of the cardiac glycosides" and "is intended to refer to any product manufactured, marketed, sold, distributed, licensed, advertised, promoted, analyzed and tested by Amide Pharmaceutical, Inc., or any Actavis Entity . . . worldwide, including but not limited to the trade name Digitek®." [Emphasis supplied.] Thus the subpoena covers Gibraltar's documents and records relating to any Actavis product produced anywhere in the world, not just the Little Falls plant in New Jersey.

Rule 45, *Fed. R. Civ. P.*, does not prohibit the service of a subpoena to produce documents which are not relevant to the case. However, Rule 45(c)(1), *Fed. R. Civ. P.*, provides that "[a] person or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on



a person subject to the subpoena.” The recipient of the subpoena is the entity or person who may serve a written objection to the subpoena if production is unduly burdensome or expensive, pursuant to Rule 45(c)(2)(B), not the party opposing issuance of the subpoena. Gibraltar has not, as far as the undersigned can determine, served a written objection.

#### Issues Raised

As noted above, Defendants’ motion to quash or modify asserts that the subpoena “requires disclosure of ‘privileged or other protected matter’ under Pretrial Order #12 and Federal Rule of Civil Procedure 45(c)(3)(A)(iii).” (## 134, at 1, 2.) Therefore, the issues raised by the motion to quash or modify are as follows: (1) does the subpoena call for production of “privileged or other protected matter” under Pretrial Order # 12? (2) does the subpoena call for production of “privileged or other protected matter” under Rule 45(c)(3)(A)(iii)?

#### Pretrial Order # 12

PTO # 12 does not use the language, “privileged or other protected matter.” The court **FINDS** that Defendants’ assertion to the contrary is unpersuasive. Thus the answer to the first question is literally “no.”

Defendants contend that PTO # 12 gives them the right to review all of Gibraltar’s documents responsive to the subpoena prior to Gibraltar’s production. They assert that they “are

entitled by the Protective Order to redact 'information relating to products other than Digitek®.'" (# 134, at 4, n.1.)

PTO # 12 gives the "Supplying Party" the right to redact "any information relating to products other than Digitek®, unless manufacturing information about a product other than Digitek® is reasonably related to Digitek® manufacturing." PTO # 12, II.F.4. In Pretrial Order # 27, the court ruled that "reasonably related to Digitek® manufacturing" includes "records of Little Falls production and the use of equipment for products other than Digitek®, which immediately preceded the use of that equipment for the production of Digitek®." As noted above, the court has no basis to believe that Gibraltar has elected status as a "Supplying Party." However, PTO # 12, II.D. gives Defendants the right to claim that Gibraltar's documents, records and testimony are "Confidential Information," if they do so within thirty days of their receipt of such information. "[A]ll parties have an opportunity to review the information and determine whether it should be designated as confidential. Any party designating third party information as confidential shall have the same rights as a Supplying Party under this order with respect to such information." Id. Defendants claim that this last quoted provision from II.D. transforms Defendants into a Supplying Party with the right to redact under II.F.4.

The court understands Defendants' reasoning to be this: in the

Agreement, Defendants designated all of Gibraltar's records relating to Defendants as "confidential;" pursuant to PTO # 12 II.D., Defendants thereby have the same rights as a Supplying Party; a Supplying Party can redact under PTS # 12 II.F.4; therefore, Defendants have the right to review and redact Gibraltar's records prior to production.

The first paragraph of PTO # 12 II.F. provides that the purpose of redaction is "[t]o protect against unauthorized disclosure of Confidential Information, and to comply with all applicable state and federal laws and regulations." "Confidential Information" is a defined term in PTO # 12, incorporates Rule 26(c), and is much narrower than the definition of "Confidential Information" in the Agreement between Actavis Totowa and Gibraltar. Thus Defendants' first premise is flawed; a third party's records must be designated in good faith as "Confidential Information" within the meaning of PTO # 12 before section II.F is triggered. The mere fact that Actavis Totowa and Gibraltar have a confidentiality agreement does not prove that Gibraltar's records constitute "Confidential Information" as defined by PTO # 12.

Once a third party's records have been designated by a party as containing "Confidential Information" as defined by PTO # 12, then and only then does the party step into the shoes of a Supplying Party and acquire the right to redact. Only certain categories of documents qualify for possible redaction: "highly

confidential trade secrets," "highly confidential business and proprietary information related to sales data," non-Digitek® product data and personal identifiers.

The labeling of a document, record or testimony as "Confidential Information," triggers certain requirements as to the handling of that information, and helps to protect against its unauthorized disclosure outside of this litigation, but it does not prevent its publication to the Receiving Party. Redaction, on the other hand, is an attempt to withhold the entirety of a given piece of information from the Receiving Party.

Based on PTO # 12, the court **FINDS** that there are two categories of documents, records and testimony which should be produced by Gibraltar pursuant to the subpoena: (a) those which are directly and "reasonably related" to Digitek® manufacturing at Little Falls; and (b) everything else. Defendants have explicitly stated that they do not object to Gibraltar's disclosure of Digitek®-related documents. (# 134, at 1, 2.) The former category is not subject to pre-production review and redaction; it could be designated as "Confidential Information" by Defendants during the 30-day post-production period, if appropriate. The second category, "everything else," is producible unless it is appropriately designated by Defendants as "Confidential Information" as defined by PTO # 12. If Defendants designate some of Gibraltar's documents as "Confidential Information," then

Defendants may review those documents for possible redaction prior to production to Plaintiffs. In other words, good faith designation of Gibraltar documents as "Confidential Information" is a condition precedent to pre-production review and possible redaction of those designated documents. The court notes that if Actavis Totowa gave Gibraltar information which constitutes "highly confidential trade secrets" or "highly confidential business and proprietary information," Actavis Totowa should know it, thus simplifying the process of identifying some Gibraltar documents as "Confidential Information."

Rule 45(c) (3) (A) (iii)

Turning now to Defendants' assertion that the subpoena "requires disclosure of 'privileged or other protected matter' under . . . Federal Rule of Civil Procedure 45(c) (3) (A) (iii)," the court notes that Rule 45(c) (3) (A) (iii) requires a court to quash or modify a subpoena if the subpoena requires disclosure of "privileged or other protected matter, if no exception or waiver applies." [Emphasis supplied.] Rule 45(c) (3) (B) (i) permits a court to quash or modify a subpoena if the subpoena requires disclosure of "a trade secret or other confidential research, development, or commercial information."

The court is unpersuaded by Defendants' assertion. It is plain that Rule 45's use of the phrase "privileged or other protected matter" refers to privileges recognized by the common law

and *Fed. R. Evid.* 501 and 502, such as the attorney-client privilege. Defendants have offered no theory of "privilege" as recognized by either the common law or *Federal Rules of Evidence* 501 or 502. Rather it appears that Defendants are attempting to transform what may be "Confidential Information" under PTO # 12 into "privileged or other protected matter" by slapping a "privilege" label on it. Similarly, at this point Defendants have failed to meet their burden to show that Gibraltar's records, documents and testimony will actually disclose a "trade secret or other confidential research, development, or commercial information."

#### Ruling

Plaintiffs have suggested that the court should review the documents produced by Gibraltar *in camera* to determine whether they should be disclosed to Plaintiffs. The court emphatically declines to do so.

It is hereby **ORDERED** that the stay of the subpoena to Gibraltar is lifted and Defendants' motion to quash or modify the subpoena is denied except as follows: pursuant to PTO # 12, sections II.D. and II.F.4., Defendants have the right to designate those records of Gibraltar which they deem to meet the PTO # 12 definition of "Confidential Information." If Defendants designate some of Gibraltar's records as "Confidential Information," then Defendants have the right, pre-production to Plaintiffs, to review

and, if appropriate, redact Gibraltar's records and documents as permitted by PTO # 12.

It is the court's expectation that Gibraltar will promptly produce to Plaintiffs and to Defendants all its records relating to Digitek®, and all its records relating to manufacturing information about a product other than Digitek® which is "reasonably related" to Digitek® manufacturing as that phrase is now defined in Pretrial Order # 27. This will probably require Defendants to identify for Gibraltar the product batches the production of which immediately preceded the production of Digitek® batches, using any of the same equipment. If Defendants believe in good faith that Gibraltar's records which are directly and reasonably related to Digitek® manufacturing contain "Confidential Information" as defined in PTO # 12, Defendants will have thirty days after production in which to designate the records as "Confidential Information," and Plaintiffs have the right to dispute the designation.

With respect to documents covered by the subpoena which relate to products other than Digitek® and which are not reasonably related to Digitek® manufacturing, that is, "everything else," Defendants have the right to designate as "Confidential Information" those documents which meet the definition in PTO # 12, to review them prior to production to Plaintiffs and to redact them as permitted by PTO # 12. The court expects the review and redaction process to move expeditiously. Plaintiffs retain their

right "to seek an order for good cause shown compelling production of information redacted pursuant to . . . paragraph [II.F]."

The Clerk is directed to file this Order in 2:08-md-1968 which shall apply to each member Digitek®-related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:09-cv-00757. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at [www.wvsd.uscourts.gov](http://www.wvsd.uscourts.gov).

ENTER: July 1, 2009

  
Mary E. Stanley  
United States Magistrate Judge